IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION — MDL NO. 2327

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL ADVAMED'S RESPONSE TO SUBPOENAS

NOW COME Plaintiffs who file this Memorandum of Law in Support of Plaintiffs' Motion to Compel AdvaMed's Response to Plaintiffs' Subpoenas.

PRELIMINARY STATEMENT

Defying a valid Subpoena *ad testificandum* and *duces tecum*, Advanced Medical Technology Association ("AdvaMed"), seeks to evade inquiry by oral deposition and shield the entirety of materials relevant to this litigation under a blanket of spurious First Amendment privilege. Although it is a non-party, AdvaMed maintains an alter-ego relationship with Ethicon in the transvaginal mesh arena. It is through this relationship that Ethicon employees on AdvaMed's platform presented inaccurate information regarding the safety, risks, and efficacy of transvaginal products—the very information that was targeted for dissemination to the general public. Plaintiffs respectfully request that AdvaMed's Objections to their Subpoena be overruled.

PROCEDURAL HISTORY

Since the summer of 2012, Plaintiffs have, in good faith, sought AdvaMed's cooperation and fulfillment of AdvaMed's pledge to produce documents in this litigation and sister litigation

in the matter of *In re: Pelvic Mesh/Gynecare Litigation*, New Jersey 291 CT.[1] These events are delineated chronologically:

On July 24, 2012, Plaintiffs served a Third-Party Subpoena *ad testificandum* and *duces tecum* on AdvaMed.[2] The subpoena was narrowly tailored and requested materials related to (1) transvaginal mesh products from 2005 to present; (2) materials related to the presentation AdvaMed made to the Obstetrics and Gynecology Device Panel [FDA] on September 8 and 9, 2011; (3) materials related to the Transvaginal Mesh Industry Working Group formed by AdvaMed which includes these defendants; and (4) documents relating to the regulatory approval, safety and efficacy of transvaginal mesh. These documents form the very core of Plaintiffs' allegations in the Master Complaint.[3]

On August 3, 2012, Allen Gardner, Esq. of Latham & Watkins, representing AdvaMed, served AdvaMed's objections to the Subpoena on Bryan F. Aylstock.[4] AdvaMed asserted four primary objections: (1) the Subpoena "seeks massive discovery";[5] (2) Discovery creates an "undue burden and expense on AdvaMed"[6] and demanded that plaintiffs establish that they need AdvaMed materials; (3) that the documents sought are protected under a variety of privileges and immunities;[7] and (4) that the Subpoena was issued from a court without "jurisdiction over AdvaMed in violation of Federal Rule of Civil Procedure 45."[8]

---

[1] *See* Ex. A, ETH.MESH.04556164 – 68
[2] *See* Ex. B, Plaintiffs' Subpoena dated July 24, 2012.
[3] *See e.g.* Ex. C, Master Complaint, ¶¶29 (high failure rate of mesh products); 30 (Defendants underreported and withheld information regarding propensity of failure for mesh products); 33 (FDA issued 2008 Health Notice describing more than 1000 adverse events); 35 (FDA concluded that it was not clear whether repair of SUI with mesh is more effective than traditional non-mesh repair).
[4] *See* Ex. D, August 3, 2012 Cover Letter from Allen Gardner to Bryan F. Aylstock enclosing AdvaMed's Objections and Responses to Plaintiffs' Rule 45 Subpoena.
[5] Ex. E, August 3, 2012 AdvaMed's Objections and Responses to Plaintiffs' Rule 45 Subpoena, at p. 2.
[6] Ex. E at p. 3.
[7] Ex. E at p. 3.
[8] Ex. E at p. 3.

On September 17, 2012, on behalf of the Plaintiffs' Steering Committee, Rayna Kessler wrote Mr. Gardner in an attempt to resolve AdvaMed's objections.[9]

On September 24, 2012, Mr. Gardner continued to assert that "AdvaMed remains willing to produce documents in response to these subpoenas if we are able to agree on the proper scope of your requests."[10] Mr. Gardner then asserted that the subpoenas were "exceedingly vague and overbroad" and "[m]ore problematically . . . appear to seek [material] protected by the First Amendment privilege."[11]

On September 23, 2012, the parties held a meet and confer with AdvaMed's counsel, during which, and for the first time, AdvaMed asserted that despite Plaintiffs' willingness to provide a new subpoena that would address concerns regarding scope, cost, and vagueness, AdvaMed refused to produce any nonpublic internal communications and stands by the assertion that the First Amendment excuses AdvaMed from complying with Plaintiffs discovery request.[12]

On October 22, 2012, Plaintiffs held a telephone meet and confer with Allen M. Gardner, of Latham & Watkins, regarding Objections raised by AdvaMed, in the "hope of narrowing our areas of disagreement over the scope of discovery served on AdvaMed."[13]

In a good faith effort to resolve the parties' dispute in advance of submitting the issue to this Court, the Plaintiffs revised their subpoena to narrow the scope. AdvaMed again objected to the venue.

On December 7, 2012, Bryan F. Aylstock, Esq. served a revised Subpoena for documents and testimony upon AdvaMed[14] and issued a Notice of Issuance of Subpoena upon Ethicon's

---

[9] Ex. F, September 17, 2012 Letter from Rayna Kessler to Allen Gardner.
[10] Ex. G, September 24, 2012 Letter from Allen Gardner to Rayna Kessler.
[11] Ex. G.
[12] Ex. H, September 26, 2012 Letter from Rayna Kessler to Allen Gardner
[13] Ex. I, November 7, 2012 Letter from Jeffrey Grand to Allen Gardner summarizing meet and confer of October 22, 2012.
[14] Ex. J, December 7, 2012 Plaintiffs' Subpoena.

counsel.[15] Before serving the subpoenas, Plaintiffs gave Defendant's counsel a copy of the subpoena, pursuant to the Federal Rules of Civil Procedure and counsel did not object.

Despite months of Plaintiffs' good faith efforts to narrow the discovery requests and cater to AdvaMed's requests, AdvaMed objected on December 13, 2012 to the document request again reiterating 3 of 4 of the same objections as it initially stated in August.[16] More than 20 days after the service of the subpoena, however, AdvaMed, has not filed a Motion to Quash the Subpoena for testimony nor has AdvaMed sought a protective Order with the Court.

Although the parties met and conferred on these issues, an agreement could not be reached.

STATEMENT OF FACTS

On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 adverse events that had been reported over a three-year period relating to Pelvic Mesh Products.

On May 12, 2011 Daniel Altman's article entitled "Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse" was published in the New England Journal of Medicine ("NEJM").[17] This study is referred to throughout as the "Altman Study."

On July 13, 2011 the FDA issued a "Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse."

On September 8 and 9, 2011, industry representatives testified before the Obstetrics and Gynecology Medical Devices Panel of the FDA (hereinafter "FDA OB/GYN Panel"). These

---

[15] Ex. K, December 7, 2012 Letter transmitting Notice of Issuance of Subpoena.
[16] Ex. L, 2012.12.13 AdvaMed's Objections and Response to Plaintiffs' December 7, 2012 Subpoena
[17] Ex. M , Altman, D. *Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse*, N Engl J Med 364;19 May 12, 2011.

individuals included: Jeff Secunda, Vice President, Technology & Regulatory Affairs, AdvaMed; Suzette E. Sutherland, M.D., Surgeon, Metro Urology, Adjunct Associate Professor, University of Minnesota; Piet Hinoul, M.D., Ph.D., Director, Medical Affairs, Ethicon Women's Health and Urology; Ginger Glaser, Senior Director, Global Quality & Regulatory Affairs, American Medical Systems.[18] Under AdvaMed's banner these individuals cited literature to the aforementioned FDA Panel to "support its view that the benefits outweigh the risks for surgical mesh used for POP repair."[19] Yet, subsequently, on April 5, 2012, during the deposition of Dr. Piet Hinoul in the matter of *In re Pelvic Mesh/Gynecare Litigation* in the Superior Court of New Jersey, Law Division – Atlantic County, Master Case 6341-10, Case No. 291 CT, Dr. Hinoul testified that he was acting on behalf of Ethicon and AdvaMed. In this deposition, Dr. Hinoul testified that the testimony he provided to the aforementioned FDA panel on September 8 and 9, 2011 was read from a script because he was representing AdvaMed, not just Ethicon.[20]

Subsequent to the September 2011, presentation, Plaintiffs, through discovery with Ethicon, learned that AdvaMed's presentation to the FDA panel mirrored Ethicon's "key takeaways" listed in an email days prior to the meeting.[21] The mirrored messages include:

- AdvaMed "presenting a collaborative industry view" cited a "large body of published studies to support its view that the safety and effectiveness of suburethral slings are well-established."[22]
- AdvaMed "argued that Class II special controls are sufficient and that clinical studies are not necessary for premarket evaluation."[23]

---

[18] Ex. N, September 8, 2011 Transcript of FDA OB/GYN Panel
[19] Ex. O, FDA Advisory Committee Summary of OB/GYN Device Panel on September 8-9, 2011 at p. 1.
[20] April 21, 2012 Deposition of Piet Hinoul at 107:14-20
[21] *See* Ex. P, September 6, 2011 Email from J&J Corporate Communications
[22] Ex. O at p. 3.
[23] Ex. O at p. 3.

- AdvaMed "also stated that mandatory 522 post market studies were not needed for suburethral slings currently on the market because many of these products have already been studied extensively, and studies are being undertaken for products with new features."[24]

Plaintiffs also learned through discovery that AdvaMed and Ethicon colluded in crafting a script for the presentation, selecting a female proponent of mesh to present to the FDA OB/GYN panel, and had involvement in editing other documents and submitted to the FDA.[25]

When it became apparent to Plaintiffs through discovery that AdvaMed had such a close relationship with Ethicon, Plaintiffs issued a Subpoena *Duces Tecum* to AdvaMed (July 2012). AdvaMed for nearly seven months has resisted discovery under Rule 45 and asserts spurious claims of privilege. Yet, Burt Snell, counsel for the defense, specifically stated that the defendant would not claim privilege on the matter of Dr. Hinoul's preparation for his testimony before the FDA panel on September 8 and 9, 2011.[26]

On September 11, 2012, Gary Pruden was deposed in the matter of *In re Pelvic Mesh/Gynecare Litigation* in the Superior Court of New Jersey, Law Division – Atlantic County, Master Case 6341-10, Case No. 291 CT.

In this deposition, Gary Pruden asked Dr. Hinoul to look at the entirety of evidence and to do a thorough review of all the evidence in November 2010 in advance of the publication of the aforementioned Altman study.[27]

---

[24] Ex. O at p. 3.
[25] *See* Ex. Q, August 3, 2011 Email string between AdvaMed's Jeffrey Secunda, Vice-President of Technology & Regulatory Affairs, to Ethicon employees Brian Kanerviko and Piet Hinoul (as well as Bard and AMS staff members, including presenter, Ginger Glaser) regarding the selection of a female MD for the FDA panel.
[26] *See* April 21, 2012 Deposition of Piet Hinoul at 139:1-8 and 152:5-11
[27] September 11, 2012 Deposition of Gary Pruden at 306:12 – 307:22.

LEGAL ARGUMENT

A person served with a subpoena may move for a protective order under Federal Rules of Civil Procedure 26(c). Under Rule 26(c), a court may "make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" upon a showing of good cause. Fed. R. Civ. P. 26(c). Here, AdvaMed has made no such motion.

When considering whether to grant a motion to compel, a court must consider whether the "discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1), and whether the request falls under any of the limitations listed in Fed. R. Civ. P. 26(b)(2)(C). The court must also consider the prior efforts of the parties to resolve the discovery dispute without court intervention. Fed. R. Civ. P. 37(a)(1); *Pogue,* 235 F.R.D. at 529-30. "[T]rial courts exercise considerable discretion in handling discovery matters[.]" *Food Lion, Inc., v. United Food and Commercial Workers Int'l Union*, 103 F.3d 1007, 1012 (D.C. Cir. 1997).

I. THE COURT SHOULD COMPEL ADVAMED TO PRODUCE THE DEPONENT SUBPOENAED.

Plaintiffs served AdvaMed with a valid Subpoena *Ad Testificandum* setting the corporate deposition of AdvaMed on December 27, 2012, at 10:00 a.m., in Washington, D.C.[28] AdvaMed failed to appear for said deposition. Generally, a motion to quash or modify a subpoena must be made before the subpoena's return date. *Estate of Ungar v. Palestinian Authority*, 451 F. Supp. 2d 607, 610 (S.D.N.Y. 2006). AdvaMed has failed to file a Motion to Quash under Fed R. Civ. P. 45(c); failed to file a Motion to Modify and failed to seek a protective Order prior to the expiration of the return date. The deposition of AdvaMed's representative should be compelled because AdvaMed failed to timely object to said deposition.

[28] Ex. J and Ex. K.

II. THE COURT SHOULD COMPEL PRODUCTION IN RESPONSE TO PLAINTIFFS' SUBPOENA

Despite months of good faith negotiations with AdvaMed and Plaintiffs, steps to resolve this discovery dispute by **narrowing** their discovery requests—AdvaMed continues to resist discovery and seeks to shield vast categories of documents under a blanket of unfounded First Amendment privilege. Plaintiffs' attempts to ascertain the basis of the privilege have proven futile as AdvaMed has not cited a single case in its communications with Plaintiffs to support its position nor has AdvaMed attempted to make a *prima facie* showing that the documents are privileged. Instead, nearly 7 months after the first Subpoena *duces tecum* was issued and despite substantial narrowing of the discovery requests, AdvaMed's objections of December 13, 2012, are nearly identical, verbatim, as the objections lodged on August 3, 2012.[29] Such indiscriminate blanket objections of irrelevance, First Amendment and over breadth should not stand.

A. AdvaMed's Objections to Production of Documents should be Overruled and AdvaMed Should Produce the Documents sought in the December 7, 2012 Subpoena.

Under Federal Rule of Civil Procedure 37, a party may "move for an order compelling disclosure or discovery" only after the "movant has in good faith conferred or attempted to confer with the person or party." Fed. R. Civ. P. 37(a)(1). Courts have held that conferring with the opposing party is a prerequisite to any successful Rule 37 motion to compel. *See U.S. ex. rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 235 F.R.D. 521, 529-30 (D.D.C. 2006). When the opposing party refused to respond to a discovery request, the burden shifts to the opposing party to show that the movant's request is burdensome, overly broad, vague, or outside the scope of discovery. *Chubb Integrated Sys. Ltd. v. Nat'l Bank of Washington*, 103 F.R.D. 52,

[29] Compare Ex. J (December 7, 2012 subpoena) with Exhibit B (former subpoena issued).

59-60 (D.D.C. 1984). Plaintiffs sought resolution of this discovery dispute with AdvaMed for more than seven months.

1. The Discovery Sought is Not Unduly Burdensome and is Relevant.

The party seeking discovery need not prove its case on the merits in order to obtain disclosure. Rather, "the burden is on the party resisting discovery to clarify and explain precisely why its objections are proper given the broad and liberal construction of the federal discovery rules." *The United Oil Company, Inc., v. Parts Associates, Inc., et al.*, 227 F.R.D. 404, 411 (D. Md. 2005) (*citing DIRECTV, Inc. v. Trone*, 209 F.R.D. 455, 458 (C.D. Cal. 2002); *Aircrash Disaster*, 172 F.R.D. 295, 307 (N.D. Ind. 1997); *Obiajulu v. City of Rochester,* 166 F.R.D. 293, 295 (W.D.N.Y. 1996); *Nestle Foods Corp. v. Aetna Cas. And Sur. Co.*, 135 F.R.D. 101 (D.N.J. 1990)). "This includes, of course, where the resisting party asserts that the discovery is irrelevant." *Chavez v. Daimler Chrysler Corp.*, 206 F.R.D. 615, 619 (S.D. Ind. 2002); *National Credit Union Admin. v. First Union Capital Markets Corp.*, 189 F.R.D. 158 (D. Md. 1999); *Schaap v. Executive Industries, Inc.,* 130 F.R.D. 384, 386 (N.D. Ill. 1990); *Spell v. McDaniel*, 591 F. Supp. 1090, 1114 (E.D.N.C. 1984).

Here, Plaintiffs' discovery requests are narrowly tailored seeking only materials (1) related to transvaginal mesh products from 2005 to present; (2) materials related to the presentation AdvaMed made to the Obstetrics and Gynecology Device Panel [FDA] on September 8 and 9, 2011; (3) materials related to the Transvaginal Mesh Industry Working Group formed by AdvaMed which includes these defendants; and (4) documents relating to the regulatory approval and safety and efficacy of transvaginal mesh. These documents are extremely relevant to Plaintiffs claims and form the very core of Plaintiffs' allegations in the

Master Complaint.[30] Certainly, if AdvaMed working in cooperation with Ethicon was substantially editing the information AdvaMed was providing to the FDA regarding safety of mesh products, Plaintiffs are entitled to discovery of this information.

Furthermore, as discussed in the Preliminary Statement of Facts, AdvaMed representatives presenting at the September 8 and 9, 2011 Panel were, in fact, employees of Ethicon. During his FDA presentation, Ethicon employee Piet Hinoul focused on the Altman study, which he considered to be the "landmark" study on transvaginal mesh.[31] Hinoul also stated that "[w]omen using mesh had an 82 percent anatomic cure rate" and that "[m]esh kits were superior for symptomatic outcome" finding "75 percent in favor of mesh versus 62 percent" for traditional surgeries.[32] Hinoul further stated that this "landmark" study that he edited for Ethicon provides "Level 1 evidence" that "transvaginal mesh kits are a valuable treatment option."[33] Hinoul was deposed in the matter of *In re Pelvic Mesh/Gynecare Litigation* and testified that he presented a "fair and balanced" presentation to the FDA.[34] Yet, Gary Pruden, Worldwide President of Ethicon Products and member of the Global Management Board, testified that Hinoul was, on behalf of Ethicon, involved in editing the Altman study.[35] Interestingly, Hinoul failed to mention to the FDA his involvement with the Altman study[36] when in fact he actually edited the Altman study before its publication.[37] Given Hinoul's testimony to the FDA on behalf of Ethicon and its alter-ego, AdvaMed, Plaintiffs are entitled to documents that may have been used in formulating, scripting or presenting data to the FDA in support of the

---

[30] *See e.g.* Ex. C, Master Complaint, ¶¶29 (high failure rate of mesh products); 30 (Defendants underreported and withheld information regarding propensity of failure for mesh products); 33 (FDA issued 2008 Health Notice describing more than 1000 adverse events); 35 (FDA concluded that it was not clear whether repair of SUI with mesh is more effective than traditional non-mesh repair).
[31] Ex. N at 143.
[32] Ex. N at 143.
[33] Ex. N at 144.
[34] *See* Deposition of Piet Hinoul at 134:12 – 135:6
[35] *See* September 11, 2012 Deposition of Gary Pruden at 306:12 – 307:22
[36] *See* Ex. N
[37] *See* September 11, 2012 Deposition of Gary Pruden at 306:12 – 307:22

safety and efficacy of mesh products. Yet, AdvaMed seeks to hide its alter-ego relationship with industry behind the shield of irrelevancy. Plaintiff has made a preliminary showing of relevancy; thus, here, AdvaMed bears the burden of demonstrating that lack of relevance and has failed to show that the discovery is outweighed by any potential harm.

i. *AdvaMed Bears the Burden of Showing That the Discovery is Unduly Burdensome.*

In determining whether a discovery request is oppressive or imposes an undue burden, a court must balance the party's need for the discovery against the potential hardship to the subject of the subpoena. *Alexander v. FBI*, 186 F.R.D. 71, 75 (D.D.C. 1998). To determine whether there is an "undue burden" a court examines "relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed." *Flatow v. Islamic Republic of Iran*, 196 F.R.D. 203, 206 (D.D.C. 2000), *vacated in part and affirmed in part on other grounds*, 305 F.3d 1249 (D.C. Cir. 2002).

Here, the documents Plaintiffs seek are narrowly tailored to a discrete time frame, narrowly target transvaginal mesh products and specific presentations made by AdvaMed. These materials are described with particularity in the Subpoena and, as discussed *supra* and *infra* (Section ii), are relevant to Plaintiffs' core allegations against the Defendants. Defendants cannot show that the materials sought are unduly burdensome.

ii. *The Materials Plaintiffs Seek Are Relevant.*

To compel production in response to a subpoena, the party seeking enforcement must make a threshold showing that discovery is relevant to its claims or defenses. *See e.g. Hofer v. Mack Trucks*, 981 F.2d 377, 380 (8th Cir. 1992), *McCoy v. Whirlpool Corp.*, 214 F.R.D. 642, 643 (D. Kan. 2003); *Chavez v. DaimlerChrysler Corp.*, 206 F.R.D. 615, 619 (S.D. Ind. 2002); *Tucker*

v. Ohtsu Tire & Rubber Co., 191 F.R.D. 495, 497 (D. Md. 2000). Relevance is construed broadly. As a result, the standard of relevancy under Rule 26(b)(1), is extremely broad and the information requested need only be germane and conceivably helpful to plaintiff. 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, *Federal Practice and Procedure* § 2008 (3d ed. 2010 & Supp. 2012).

The Defendant in the present action is a member company of AdvaMed. The discovery materials Plaintiffs seek consists of documents relating to the risks, safety, and efficacy of transvaginal surgical mesh products. AdvaMed possesses materials responsive to Plaintiffs' request and, because they are relevant to the present action, AdvaMed should produce them.

2. The Discovery Sought Does Not Impose a Discovery Obligation greater or Inconsistent with those Imposed by the Federal Rules of Civil Procedure.

Contra to AdvaMed's general objection no. 2 set forth in its December 13, 2012 Objections to Plaintiff's Subpoena,[38] the discovery Plaintiffs seek does not impose a discovery obligation greater or inconsistent with the Federal Rules of Civil Procedure. AdvaMed has failed to file a Motion to Quash the Subpoena *duces tecum* or even attempt to limit the scope of testimony to be taken under the Subpoena under Fed. R. Civ. P. 30. The only limitations against subpoenas *ad testificandum* and *duces tecum* are the limitations provided under Fed. R. Civ. P. 45 and relief sought under Fed. R. Civ. P. 30(b). AdvaMed has not taken any steps to quash the subpoena *ad testificandum* or sought a protective order; thus, its objections claiming blanket inconsistency with the Federal Rules while sitting back and doing nothing pro-actively with regard to the Subpoena are disingenuous.

[38] Ex. L, December 13, 2012 AdvaMed's Objections to Plaintiffs' Subpoena

3. AdvaMed Has Not Established and Cannot Establish That the Information and Documents Sought by Plaintiffs are Privileged and Protected from Disclosure by the First Amendment or any other Privilege.

AdvaMed seeks to shield its disclosure by casting a blanket of First Amendment privilege over all the materials Plaintiffs seek.[39] Yet, pursuant to Rule 45(d)(2) when subpoenaed information is withheld based on a claim of privilege, the claim of privilege must "describe the nature of the privilege withheld [information] in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim." Fed. R. Civ. P. 45(d)(2). Instead of describing such information here or moving for a protective order, AdvaMed claims privilege over all materials. Despite the fact that Plaintiffs narrowed the scope of the requests, AdvaMed asserts the same objections in December of 2012 [following revision of the Subpoena] as it asserted in July of 2012. For instance, in July 2012, at the beginning of the meet and confer process, without citing supportive case law, AdvaMed asserted the material Plaintiffs request is protected by the First Amendment and is "core protected speech."[40] Subsequently, AdvaMed rested on *AFL-CIO v. FEC*, 333 F.3d 168 (D.C. Cir. 2003) to support the assertion that the First Amendment privilege applies; then on September 25, 2012, AdvaMed agreed that *AFL-CIO* is irrelevant.[41] AdvaMed cannot support its claims of First Amendment privilege.

i. The First Amendment Protects Against Disclosure of Information Only in the Very Limited Circumstances Where Disclosure Would Subject Members To the Risk of Reprisal For Their Protected Activity or Would Chill Freedom of Association.

The First Amendment protects individuals from being punished for or prohibited from exercising their right to speak and to associate freely. Except in very narrowly defined circumstances, the First Amendment does not provide a shield against disclosure of

[39] *See e.g.* Ex. L (December 13, 2012 objections at General Obj. #3 and Request No. 1).
[40] *See e.g.* Ex. E & Ex. L.
[41] Here, *AFL-CIO v. FEC is inapplicable because* Plaintiffs are private individuals seeking relevant discovery from a private trade association whose documents it is being asked to produce are subject to the litigation's protective orders which prohibit their public dissemination.

information.[42] The narrow circumstances in which the First Amendment may protect against disclosure of information were defined by the Supreme Court in *NAACP v. Alabama,* 357 U.S. 449 (1958). In that case, where there was substantial evidence that disclosure of membership in an organization would subject the members to the risk of harm and would impair the ability of the organization to advocate for the beliefs of its members, the First Amendment required that the information be protected against disclosure. "[C]ompelled disclosure of affiliation with groups engaged in advocacy may constitute [an] effective . . . restraint on freedom of association." *Id.* at 462. In particular, the Court cited the very real danger that the NAACP members would face physical coercion, bodily harm, economic reprisal, and loss of employment if their membership was revealed and the concordant risk that members would be induced to withdraw or others be dissuaded from joining to avoid that danger. *Id.* Similarly, in *Bates v. City of Little Rock,* 361 U.S. 516, 524 (1960), the Court reversed the convictions of individuals who refused to furnish city officials with a list of members of the local NAACP, because there was "substantial uncontroverted evidence that public identification . . . as members . . . had been followed by harassment and threats of bodily harm."

Courts following *NAACP* have interpreted the discovery privilege narrowly, limiting it to requests for volunteer lists, financial contributor lists and similar information at the "core of the group's associational activities."[43] In fact, in *Wyoming v. United States Dep't of Agriculture,* 239 F. Supp. 2d 1219 (D. Wyo. 2002), *vacated as moot,* 414 F.3d 1207 (10th Cir. 2005), the court

---

[42] *Wilkinson v. FBI,* 111 F.R.D. 432, 436 (C.D. Cal. 1986) ("the privilege is not available to circumvent general discovery"); *Anderson v. Hale,* 2001 WL 503045 at *7, (N.D. Ill. 2001) (noting the Supreme Court "did not intend to provide publicly identified members of dissident organizations with a nearly impenetrable shield . . . to block general discovery requests").

[43] *Wilkinson v. Federal Bureau of Investigation,* 111 F.R.D. 432, 436-437 (C.D.Ca. 1986) (no First Amendment privilege to avoid producing record of political activities and associations of civil rights activist and members of the National Committee to Abolish the House Un-American Activities Committee; "the First Amendment associational privilege has been applied only in situations where the discovery request specifically required disclosure of the names of a group's members or financial contributors")

affirmed a magistrate's ruling requiring disclosure of internal and inter-group lobbying efforts and political planning and strategy sessions. The court emphasized that the magistrate's order did not require disclosure of the defendants' "internal associational activities, i.e., membership lists, financial contributor lists, volunteer lists, or past political activity of its anonymous individual members." 239 F. Supp. 2d at 1239. When a party asserting a First Amendment "associational privilege" seeks to protect material outside those core "internal associational activities," it must demonstrate that if the materials were disclosed, "active members will leave, or prospective members will not join, the organization for fear of threats, harassment, or reprisal." *Id.* at 1238.9. AdvaMed can make no such showing here.

Similarly, in *McCormick v. City of Lawrence, Kansas,* 2005 WL 1606595, at * 7 (D. Kan. July 8, 2005), the court refused to apply the First Amendment associational privilege to a discovery request for information relating to "activities of [various political or quasi-political organizations] that were intended to be confidential, and correspondence with those with whom he associated and spoke to for the purpose of assisting them with litigation aimed at vindicating civil rights." The court noted that "Plaintiff does not ask the court to protect documents relating to core associational concerns such as membership lists or even names, but rather seeks to prevent any discovery of his files. The associational privilege simply is not that broad." *Id.* at * 8.[44] The "privilege" recognized in *NAACP v. Alabama* cannot be invoked simply by refusing to disclose information or documents on the basis of the "First Amendment privilege." The party asserting the privilege bears the burden of proving a "reasonable probability" that disclosure would lead to the types of harm identified by the Supreme Court. *Buckley v. Valeo,* 424 U.S. 1,

[44] *See also Anderson v. Hale, supra,* (associational privilege does not preclude disclosure by internet service providers of information in known members' possession about conspiracy because "the risk of inducing present members to withdraw or of discouraging potential members from joining [was] too speculative to warrant heightened scrutiny under the First Amendment." 2001 WL 503045 at *6. Discovery was essential to prove conspiracy; to hold otherwise would create an impenetrable shield to even routine discovery.)

74 (1976). The Supreme Court has stated that parties must establish those threats through specific evidence: The proof may include, for example, specific evidence of past or present harassment of members due to their associational ties, or of harassment directed against the organization itself. A pattern of threats or specific manifestations of public hostility may be sufficient. New parties that have no history upon which to draw may be able to offer evidence of reprisals and threats directed against individuals or organizations holding similar views. *Id.* Even if a party has made out a prima facie case, the privilege is not absolute and discovery may be outweighed by the other party's interest in obtaining the documents or information. *Silkwood v. Kerr-McGee Corp.*, 563 F.2d 433, 438 (10th Cir. 1977). AdvaMed has made no such showing.

ii. *AdvaMed Has Not Made Out a Prima Facie Case That the First Amendment Privilege Applies.*

AdvaMed has not made out a prima facie case for the privilege. During the parties meet and confer communications, AdvaMed offered nothing other than the bare invocation of the words "First Amendment privilege." That invocation cannot suffice for the prima facie case required by the Supreme Court. Even if AdvaMed had said more, they would not qualify for the privilege. The discovery here isn't aimed at the "core of the group's associational activities." *Wilkinson v. F.B.I., supra,* 111 F.R.D. at 436. The focus of Plaintiffs' Requests is not the volunteer lists, contributors or internal operations of these trade organizations; it is instead on each Defendant and its knowledge and activities with regard to the negligence of the Defendants with regard to transvaginal mesh. Rather, Plaintiffs seek information and writings that demonstrate what the defendants knew about the availability, feasibility and legality of transvaginal mesh, when they knew it, and what they did with it.

The requested discovery does not implicate the First Amendment concerns identified in *NAACP v. Alabama* of a potential chilling effect posed by threats and retaliation. Membership in

trade associations is reserved for those already in the industry-entities and people with commercial interests. Generally members join trade associations to enhance, not conceal, their public image. AdvaMed has not shown that revealing the requested information will result in serious reprisals that target members based on their association. AdvaMed has not shown that these requests and responses thereto are likely to have a chilling effect on such a commercial defendant's rights to continue to associate with other commercial operators, nor are other members of the organizations mentioned in the discovery likely to be induced to leave for fear of reprisals.

iii. *The Balance of Interests Requires Disclosure.*

Even if AdvaMed had carried its burden of making a prima facie showing of privilege – something they have not done, the balancing of interests would favor discovery. In *Silkwood v. Kerr-McGee Corp.,* 563 F.2d 433, 438 (10th Cir.1977), the Court described factors to be considered on a assertion of associational privilege: relevance, necessity, availability and whether the party asserting the privilege has placed certain information into issue. *See also Grandbouche v. Clancy,* 825 F.2d 1463, 1466-67 (10th Cir. 1987). The balancing of those factors here compels disclosure.

Relevance and Necessity:

This discovery goes to the "heart of the matter." *Grandbouche, supra,* 825 F.2d at 1467. The questions are drawn in large part from the Defendants and AdvaMed's own contentions about safety, efficacy and the risks and benefits of transvaginal mesh. These questions are designed to identify what Defendants did and didn't know over time. Plaintiffs have alleged Defendants concealed the risks of transvaginal mesh. Thus, information shared on these subjects through trade associations is relevant, necessary and real.

Availability: Plaintiffs have carefully asked each individual Defendant about its own role, and in doing so, has elicited testimony implicating AdvaMed's intimate involvement in jointly advocating the safety of transvaginal mesh. The extent of AdvaMed's relationship and involvement cannot be supplied by anyone but AdvaMed. There is no other ready source for the information.

Defendants' waiver:

The Defendants have effectively waived any privilege by asserting in their pleadings, motion to dismiss, answers and responses to discovery that transvaginal mesh is safe and effective. Having made those representations, Defendants have put their state of knowledge and their conduct, whether consistent or at variance with that knowledge, "in issue" in this litigation. *Grandbouche, supra,* 825 F.2d at 1467. Defendants have opened the door to discovery into the merits of those defenses, and these requests and interrogatories into the activities the Defendants and AdvaMed are well-suited to that task.

If balancing of interests were required, those interests strongly favor disclosure. Defendants' First Amendment and "associational privilege" objections to discovery into their communications with one another, with others in the industry and with trade groups and industry associations should be overruled.

iv. *AdvaMed Has Not Established and Cannot Establish That Any Other Privilege Applies.*

In addition to its spurious First Amendment claim, AdvaMed has also claimed "any other applicable privilege" over the documents and deposition testimony previously subpoenaed by plaintiffs. If AdvaMed's broad claim attempts to implicate an attorney-client privilege, such a privilege claim fails for multiple reasons. First and foremost, claims of attorney-client privilege

must be made specifically.[45] "When a party withholds information otherwise discoverable by claiming that the information is privileged …, the party must: (i) expressly make the claim; and (ii) describe the nature of the documents, communications, or tangible things not produced or disclosed – and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim."[46] Obviously, AdvaMed's claim of "any other applicable privilege" does not satisfy this rule. Additionally, three basic requirements of an attorney-client privilege claim are that the communication or information is: 1) not made in the presence of a 3rd party, 2) made primarily for the purpose of legal advice, and 3) not waived by the client.[47] None of these requirements are met with respect to the documents or testimony at issue.

By way of example, a number of entries identified on Ethicon's privilege log involve meeting minutes, agendas, correspondence and other documents relating to an "FDA and AdvaMed Surgical Mesh Workgroup" of which Ethicon was a participant. Importantly, many employees of non-Ethicon entities were also participants in this working group, including individuals from AdvaMed, AMS, Bard Medical, Boston Scientific and the FDA. The participation of Ethicon's competitors and the FDA in this workgroup negates any potential attorney-client privilege claim (by any party including Ethicon or AdvaMed) over meeting minutes as well as other shared and/or related documents. Moreover, the communications at these meetings were not made primarily for the purpose of legal advice.

---

[45] Federal Rule of Civil Procedure 26(b)(5).
[46] *Id.*
[47] "The privilege applies only if (1) the asserted holder of the privilege is or sought to become a client; (2) the person to whom the communication was made (a) is a member of the bar of a court, or his subordinate and (b) in connection with this communication is acting as a lawyer; (3) the communication relates to a fact of which the attorney was informed (a) by his client (b) without the presence of strangers (c) for the purpose of securing primarily either (i) an opinion of law or (ii) legal services or (iii) assistance in some legal proceeding, and not (d) for the purpose of committing a crime or tort; and (4) the privilege has been (a) claimed and (b) not waived by the client." *United States v. United Show Machinery Corp.*, 89 F. Supp. 357, 358-359 (D. Mass. 1950).

Attached hereto is a version of draft meeting minutes from a November 22, 2011 "FDA and AdvaMed Surgical Mesh WG Meeting."[48] Ethicon redacted this document, claiming that the redacted portions reflect "Ethicon Legal Department's legal analysis and maintaining common defense regarding FDA panel meeting." However, these meeting minutes are identified on Ethicon's privilege log as being authored by G. Glaser (AMS) and J. Secunda (AdvaMed), and no recipients or "cc's" are identified for this document. The document itself indicates that nine FDA employees as well as representatives from AdvaMed, AMS, Bard Medical, and Boston Scientific were also present at this November 22, 2011 meeting. In fact, one of the redacted portions of the meeting minutes is titled "FDA Response."[49] Contrary to requirements of the attorney-client privilege, this communication or information is: 1) made in the presence of a 3rd party, 2) not made primarily for the purpose of legal advice, and 3) waived by the client inasmuch as it was communicated to other parties.

CONCLUSION

For the reasons stated above, the Court should grant Plaintiffs' Motion to Compel AdvaMed's Response to Subpoenas.

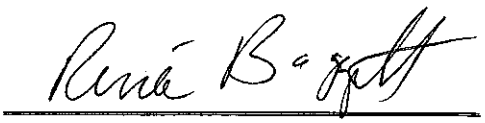
Respectfully submitted,

D. Renee Baggett
AYLSTOCK WITKIN KREIS & OVERHOLTZ, PLLC
Florida Bar No.: 38186
17 E. Main St., Ste. 200
Pensacola, Florida 32502
Telephone: 850.202.1010
Facsimile: 850.916.7449
rbaggett@awkolaw.com

[48] Ex. A, ETH.MESH.04556164 – 68
[49] *See* Ex. A at p. 3, ETH.MESH.04556166

CERTIFICATE OF SERVICE

I certify that on the 14th day of January 2013, I electronically filed the foregoing Pleading with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record and that a copy was sent electronically to Allen M. Gardner, Latham & Watkins, LLP, 555 Eleventh Street, NW, Suite 1000, Washington, DC 20004-1304, allen.gardner@lw.com.



D. Renee Baggett